

REMARKS

In response to the Office Action mailed on January 22, 2008, Applicant respectfully requests reconsideration in view of the foregoing amendments and the following remarks. Claims 2-9 and 12-21 were previously pending in this application; withdrawn claims 10, 11, 22 and 23 have been canceled. Claims 2-9 and 12-21 are amended; claims 24 and 25 have been added. Thus, claims 2-9, 12-21 and 24-25 are pending for examination with claims 2 and 12 being independent. No new matter has been added.

Claim Objections

Claims 2 and 12 have been objected to on the basis that the word "therethrough" is misspelled. Applicant has amended claims 2 and 12 to correct the misspelled word, such that the objection should be withdrawn.

Claim Rejections – 35 U.S.C. 112

Claims 3 and 15 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite. In particular, the examiner indicates that it is unclear how the treatment accessory is non-detachable and integrated at the distal end of the endoscope shaft, as recited in claims 2 and 12, and also mounted over a portion of the endoscope, as recited in claims 3 and 15.

Applicant has amended claims 3 and 15 in a manner believed to address the examiner's concern. In particular, claims 3 and 15 have been amended to recite that the a tissue apposition device includes a cylindrical cartridge that is integrated over a reduced diameter portion of the endoscope shaft. Applicant respectfully submits that claims 3 and 15 are clear in view of claims 2 and 12, such that the rejection under §112 should be withdrawn.

Claim Rejections – 35 U.S.C. 102

Claims 2-4, 6, 12-16 and 18 have been rejected under 35 U.S.C. 102(b) as being anticipated by Solar (U.S. Patent No. 5,947,983). Applicant respectfully traverses the rejection.

Independent claim 2 is directed to an endoscope comprising an endoscope shaft having proximal and distal ends and one or more uninterrupted lumens extending therethrough, a non-

detachable treatment accessory integrated at the distal end of the shaft, a non-detachable housing for the accessory integrated into the endoscope shaft, one or more accessory control elements extending through the one or more lumens of the endoscope shaft, and an accessory control mechanism mounted at the proximal end of the endoscope. The treatment accessory comprises a tissue apposition device comprising at least one suction port and at least one needle movable through the accessory to penetrate tissue aspirated into the suction port.

Without acceding to the characterization of the device set forth in the Office Action, Applicant respectfully submits that the Solar device is not an integrated endoscope as recited in the claim. An endoscope is a well known medical instrument for visually examining the interior of a body cavity or hollow organ, which includes a rigid or flexible shaft fitted with a lens and a light source, such as fiber optics, for viewing. One or more working channels may extend through the shaft to provide passage of a separate tool or treatment accessory from the distal end of the shaft.

As indicated above, claim 2 is directed to an endoscope that includes a *non-detachable* treatment accessory *integrated* at the distal end of the shaft, and a *non-detachable* housing for the accessory *integrated* into the endoscope shaft. In this regard, the endoscope and the treatment accessory are integrated into a single unit.

Solar discloses a tissue cutting and stitching device 100 for cutting tissue from a body lumen. The device comprises multiple catheter tubes 110, 120, 130 that are movable within each other, and a helical needle 140 that may be advanced within the second tube 120. However, in contrast to the examiner's assertion, the Solar device is *not* an endoscope with a non-detachable treatment accessory integrated at the distal end of an endoscope shaft and a non-detachable housing for the accessory integrated into the endoscope shaft. The Solar device is *not* designed for visually examining the interior of a body cavity or hollow organ. Rather, Solar expressly indicates that the cutting device is introduced into a body lumen either through a working channel of an endoscope or over the exterior surface of an endoscope, or without the use of an endoscope. (Col. 5, lines 12-23). Thus, one of ordinary skill in the art would readily understand that the Solar device is not an endoscope, let alone an integrated endoscope and treatment accessory as recited in claim 2. Accordingly, the rejection of claim 2 under §102 is improper and should be withdrawn for at least this reason.

Claims 3-4 and 6 depend from claim 2 and are patentable for at least the same reasons.

Independent claim 12 is directed to a method of performing an endoscopic medical procedure. The method comprises, *inter alia*, providing an endoscope comprising an endoscope shaft having proximal and distal ends and one or more uninterrupted lumens extending therethrough; a non-detachable treatment accessory integrated at the distal end of the shaft, wherein the treatment accessory comprises a tissue apposition device comprising at least one suction port and at least one needle movable through the accessory to penetrate tissue aspirated into the suction port; a non-detachable housing for the accessory integrated into the endoscope shaft; one or more accessory control elements extending through the one or more lumens of the endoscope shaft; and an accessory control mechanism mounted at the proximal end of the endoscope.

As indicated above concerning claim 2, Solar does not teach or suggest a method that involves providing an integrated endoscope and treatment accessory as recited in the claim. Rather, Solar discloses a tissue cutting and stitching device that is introduced into a body lumen either through a working channel of an endoscope or over the exterior surface of an endoscope, or without the use of an endoscope. Accordingly, the rejection of claim 12 under §102 is improper and should be withdrawn for at least this reason.

Claims 13-16 and 18 depend from claim 12 and are patentable for at least the same reasons.

Claim Rejections – 35 U.S.C. 103

Claims 2-3, 7-9, 12-15 and 19-21

Claims 2-3, 7-9, 12-15 and 19-21 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Gambale (US Patent Application No. 2003/0208209). Applicant respectfully traverses the rejection.

Independent claims 2 and 12 are discussed above.

Gambale discloses an endoscopic tissue apposition device that includes a capsule that is detachably mountable to the distal end of an endoscope. As acknowledged by the examiner, Gambale does not disclose an integrated endoscope including a treatment accessory that is non-detachably integrated at the distal end the endoscope shaft as required by the claims. (Office Action, page 5). However, the examiner contends that it would have been obvious to one of

ordinary skill in the art at the time of the invention to have integrated the Gambale treatment accessory to the distal end of the endoscope shaft because forming an article in one piece that has formerly been formed in two pieces and put together involves only routine skill in the art, citing Howard v. Detroit Stove Works, 150 U.S. 164 (1893). Applicant respectfully disagrees.

The Office Action impermissibly relies on a per se rule of patentability.

The examiner relies on the Howard decision for a purported “rule” that forming an article in one piece that has formerly been formed in two pieces and put together involves only routine skill in the art. The rejection is legally unsupportable.

The rejection relies on a purported *per se* rule of patentability. The Federal Circuit has held that such *per se* rules have no force. See e.g., In re Ochiai, 37 USPQ 2d 1127, 1133 (Fed. Cir. 1995) (“The use of *per se* rules...flouts §103 and the fundamental case law applying it”). Consequently, to support a rejection, an examiner must specifically identify, from the prior art or common knowledge in the art, the apparent reason to make the claimed invention. There is no shortage of Federal Circuit cases reversing rejections for failure to do so. See e.g., In re Dembiczak, 175 F.3d 994, 50 USPQ2d 1614 (Fed. Cir. 1999) (reversing rejection because specific motivation in the prior art not identified).

The record is devoid of any apparent reason to modify Gambale.

Once the Howard *per se* rule is removed as legal error, nothing is left to support the rejection of the claims. The examiner merely concludes that the claims would have been obvious based solely on a court decision rendered in 1893 for an invention completely unrelated to the present claims. This is improper. As the Federal Circuit has explained, there must be some articulated reasoning with some rational underpinnings to support the legal conclusion of obviousness. See In re Kahn, 441 F. 3d 977, 998 (Fed. Cir. 2006), cited approvingly by the Supreme Court in KSR International Co. v. Teleflex Inc., 550 US (2007). The record is simply devoid of any teaching, suggestion or other apparent reason that would have led one of ordinary skill in the art at the time of the present invention to modify Gambale to provide an integrated endoscope in which the tissue apposition device is non-detachably integrated into the endoscope shaft as recited in the claims.

One of ordinary skill in the art would not have been led to modify Gambale as suggested.

Applicant respectfully submits that one of ordinary skill in the art would not have been led to modify Gambale in the manner suggested in the Office Action. As described above, Gambale discloses a tissue apposition device with a suturing capsule that is mountable to the distal end of an endoscope. In this manner, the apposition device may be used with a conventional endoscope that would typically be used by an endoscopist for carrying out various endoscopic procedures, including procedures unrelated to tissue apposition. As one of ordinary skill in the art would readily appreciate, an integrated endoscope with a non-detachable treatment accessory integrated into the endoscope would have a limited application dedicated to tissue apposition. Such a device may not be considered desirable as it would not have the flexibility for various endoscopic applications as provided by conventional endoscopes.

Additionally, Gambale expressly indicates that an object of his invention was to provide an endoscopic apposition device that is simple and economical to fabricate by injection molding techniques. (page 4, ¶0029). As one of ordinary skill in the art would readily appreciate, modifying the Gambale apposition device such that it would be a non-detachable integrated component of an endoscope would be in direct contrast to Gambale's desire to provide a simple and economic device. Rather, it would involve a more complex and expensive tissue apposition device.

A *prima facie* case of obviousness has not been established.

In view of the foregoing, Applicant respectfully submits that a *prima facie* case of obviousness has not been established in the Office Action. Gambale does not provide any apparent reason that would have led one of ordinary skill in the art to modify the tissue apposition device in the manner suggested in the Office Action. Additionally, no other factual basis supported by the record has been provided to establish a case of obviousness. Applicant respectfully submits that any assertion that it would have been obvious to modify Gambale would appear to be the result of improper hindsight reconstruction in view of Applicant's claimed invention. Accordingly, the rejection of independent claims 2 and 12 under §103 in view of Gambale is improper and should be withdrawn.

Claims 3 and 7-9 and claims 13-15 and 19-21 respectively depend from claims 2 and 12 and are patentable for at least the same reason.

Claims 5 and 7

Claims 5 and 7 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Solar in view of Allen (US Patent No. 6,626,930). Without acceding to the propriety of the combination suggested by the examiner, claims 5 and 7 depend from claim 2 and are patentable for at least the same reasons set forth above. Accordingly, the rejection of claims 5 and 7 under §103 should be withdrawn.

Additional Claims

Claims 24 and 25 have been added to further define Applicant's inventions. Claims 24 and 25 depend respectively from claims 2 and 12 and are patentable for at least the same reasons set forth above.

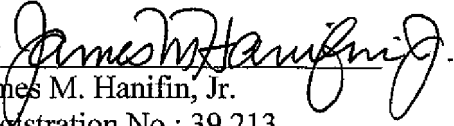
CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the undersigned at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, the Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 23/2825, under Docket No. D0188.70209US01.

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Respectfully submitted,

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